

## ORIGINAL ARTICLE

# Risk factors for a prolonged operative time in a single-incision laparoscopic cholecystectomy

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## Abstract

**Background:** A prolonged operative time is associated with adverse post-operative outcomes in laparoscopic surgery. Although a single-incision laparoscopic cholecystectomy (SILC) requires a longer operative time as compared with a conventional laparoscopic cholecystectomy, risk factors for a prolonged operative time in SILC remain unknown.

**Methods:** A total of 20 clinical variables were retrospectively reviewed to identify factors for a prolonged operative time (longer than 3 h) in a total of 220 consecutive patients undergoing SILC.

**Results:** The median operative time was 145 min (range, 55–435) and a prolonged operative time was required in 62 patients (28%). Independent factors that predict a prolonged operative time as identified through multivariate analysis were body mass index (BMI) ( $P = 0.009$ ), acute cholecystitis ( $P < 0.001$ ) and operator (resident or staff surgeon) ( $P < 0.001$ ). Furthermore, a prolonged operative time was significantly associated with an increased amount of intra-operative blood loss ( $P < 0.001$ ) and a prolonged stay after surgery ( $P < 0.001$ ).

**Conclusions:** These findings suggest that a higher BMI, acute cholecystitis and a resident as an operator significantly increase the duration of SILC procedures.

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## Introduction

A laparoscopic cholecystectomy (LC) has long been recognized as the gold standard procedure for removal of the gallbladder. Recently, a single-incision laparoscopic cholecystectomy (SILC), also called as transumbilical LC or laparoendoscopic single site (LESS) cholecystectomy, has been developed to further minimize the invasiveness of LC by reducing the number of incisions.<sup>1–3</sup> Although questions still remain as to the safety, absolute benefits and long-term outcomes of the procedure, recent randomized controlled trials have shown that SILC can provide, at least in part, better cosmetic results as compared with conventional LC.<sup>4–10</sup> On the other hand, SILC requires a longer operative time as compared with conventional LC.<sup>7,10–12</sup>

It has been recently shown that an increased operative time is associated with increased complication rates in various laparoscopic surgeries.<sup>13</sup> In conventional LC, a prolonged operative time has been reported to result in increased rates of post-operative

complications (such as bile duct injury and bleeding) and a prolonged hospital stay.<sup>14</sup> In a retrospective analysis including a total of 601 patients undergoing conventional LC, a significantly higher post-operative morbidity rate was noted in patients who had a procedure longer than 2 h than in patients whose surgery required less than 2 h (13.6% versus 3.6%,  $P < 0.001$ ).<sup>15</sup> Previous studies have identified male gender, obesity, previous upper abdominal surgery, acute cholecystitis, intra-abdominal adhesions and a low degree of surgical expertise as risk factors predicting a prolonged operative time in conventional LC.<sup>14,16</sup>

Considering that the main benefit of SILC appears to be improved cosmesis, an increased risk of post-operative complications and a prolonged hospital stay as a result of a prolonged operative time may not be justified. It is, therefore, important to understand the factors responsible for an increased operative time in SILC. In the present study, clinical variables were retrospectively reviewed to identify factors for a prolonged operative time in a total of 220 consecutive patients undergoing SILC.

## Patients and methods

### Patients

All patients who had attempted SILC from September 2009 to July 2012, at the Department of Surgery, University of Occupational and Environmental Health (Kitakyushu, Japan) were identified through a search of clinical database and hospital records. Patients were excluded if they had an additional procedure (e.g. common bile duct exploration) at the time of cholecystectomy. This series is the institution's initial experience with SILC and there were no exclusion criteria for performing SILC during the study period. The diagnosis of acute cholecystitis was made pre-operatively according to the Tokyo guidelines.<sup>17</sup> Briefly, patients exhibiting one of the local signs of inflammation (such as Murphy's sign, or a mass, pain or tenderness in the right upper quadrant), as well as one of the systemic signs of inflammation (such as a fever, elevated white blood cell count and elevated C-reactive protein level) were diagnosed as having acute cholecystitis.

### Operative procedure

The technique for SILC used was a three-trocar approach through a single umbilical incision. Under general anaesthesia, patients were placed in the supine position with their legs apart. A 2.5-cm vertical incision was made on the umbilicus, through which a 5-mm trocar (Endopath Xcel; Ethicon Endo-Surgery, Cincinnati, OH, USA) was introduced for pneumoperitoneum and a laparoscope (EndoEye camera system; Olympus Medical System, Tokyo, Japan). After exposing the abdominal fascia under the skin flap of the umbilical incision, a grasper for gallbladder retraction was directly inserted without a trocar by making a pinhole on the fascia with a needle. Then, two 5-mm trocars (Endopath Xcel, Ethicon Endo-Surgery, or EZ trocar, Hakko Co., Nagano, Japan) for the operator's manipulation were inserted into the abdominal cavity through the single umbilical incision. In some patients, a small wound retractor (Alexis wound retractor; Applied Medical, Rancho Santa Margarita, CA, USA) combined with a surgical glove (glove method) or a small wound protector (Lap-Protector, Hakko) combined with a silicon rubber cap (EZ Access; Hakko Co.) were used as a multichannel port.

Dissection of the Calot triangle was performed carefully according to the critical view of the safety approach.<sup>18</sup> After confirming that the cystic artery and cystic duct are the only two tubular structures remaining between the gallbladder and the hepatoduodenal ligament, an intra-operative cholangiography was routinely attempted. In most patients, IOC was performed using the Kumar cholangiography system (Nashville Surgical Instruments, Nashville, TN, USA).<sup>19</sup> After completion of intra-operative cholangiography, the cystic duct and cystic artery were doubly clipped with a 5-mm disposable clip applier and then divided. The gallbladder was then dissected from the liver bed using hook electrocautery or Harmonic ACE (Johnson & Johnson, Cincinnati, OH, USA). The gallbladder was then collected in a bag and removed through the umbilical incision,

usually by enlarging the fascial opening as required. The fascial defect in the umbilicus was closed using an absorbable monofilament suture and the skin was closed subcuticularly with a 4-0 absorbable monofilament suture.

### Definition of a prolonged operative time and clinical variables for comparison

A prolonged operative time was defined as the upper quartile (longer than 3 h) according to the distribution. Using this definition, all patients who underwent an attempted SILC were divided into two groups: a group of patients who had a procedure less than 3 h (no prolonged operative time group) and patients who required longer than 3 h to complete the procedure (prolonged operative time group). Clinical variables analysed were age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score ( $\geq 3$ ), comorbid diseases, diabetes mellitus, prior abdominal surgery (all), prior upper abdominal surgery, a clinical presentation of acute cholecystitis, operator (surgical residents or senior staffs), and preoperative values of white blood cell counts (WBC), total bilirubin (T. Bil.), direct bilirubin (D. Bil.), aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), gamma-glutamyl transpeptidase ( $\gamma$ -GTP) and creatinine. Factors associated with a learning curve (institution's first 100 patients and the first 10 patients for each operator) were also included in the analysis. The number of 10 for each operator was defined according to a previous study reporting a requirement of 8 procedures to achieve a learning curve plateau with SILC.<sup>20</sup>

### Statistical analysis

All statistical analyses were done using JMP 10 software (SAS Institute Inc., Cary, NC, USA). Categorical variables were analysed using Fisher's exact probability test and continuous variables were analysed using the Mann-Whitney *U*-test. Multivariate analysis was done for all variables with *P*-values of less than 0.2 using a logistic regression analysis. A *P*-value of less than 0.05 was considered statistically significant.

## Results

### Patient characteristics of study population and overall outcomes

In total, 220 patients with gallbladder diseases (including symptomatic cholelithiasis, acute cholecystitis, and gallbladder polyps) were identified as having an attempted SILC. The patient characteristics and overall outcomes of the study population are shown in Table 1.

### Identification of factors affecting a prolonged operative time in SILC

A total of 20 clinical variables were compared between the no prolonged operative time group ( $n = 158$ ) and prolonged operative time group ( $n = 62$ ) (Table 2). Multivariate analysis revealed

**Table 1** Patient characteristics and outcomes of all the study population

Factor	All patients (n = 220)
Age (years)	62 (16–91)
Gender (M/F)	91/67
BMI (kg/m <sup>2</sup> )	22.6 (13.8–46.6)
ASA score	
1	68 (31%)
2	140 (64%)
3	7 (3%)
Comorbid diseases (yes)	125 (57%)
Diabetes mellitus (yes)	34 (15%)
Prior abdominal surgery (yes)	80 (36%)
Prior upper abdominal surgery (yes)	10 (5%)
Acute cholecystitis (yes)	30 (14%)
Operator (residents/senior staff)	53/167
Operative time (minutes)	145 (55–435)
Intra-operative blood loss (ml)	5 (0–425)
Post-operative complications	9 (3%)
Wound infection	5
Aspiration pneumonia	2
Bile leakage	1
Delayed abdominal abscess	1
Post-operative hospital stay (days)	5 (2–36)

Values shown are median (range).

BMI, acute cholecystitis and operator to be independent factors predicting the prolonged operative time (Table 3).

### Correlation between prolonged operative time and operative/post-operative outcomes

Comparisons of operative time with operative and post-operative outcomes (including intra-operative blood loss, post-operative complications and length of post-operative hospital stay) revealed a significant association with prolonged operative time and increased intra-operative blood loss and a longer post-operative hospital stay (Table 4).

### Discussion

In an attempt to identify risk factors that predict the prolonged operative time in SILC, univariate and multivariate analyses were used to investigate 20 clinical variables in a total of 220 consecutive patients. The major findings of the present study were as follows: (i) a prolonged operative time (longer than 3 h) was required in 62 patients (28%); (ii) on multivariate analysis, independent factors predicting a prolonged operative time were higher BMI, acute cholecystitis and operator (resident); and (iii) a prolonged operative time was significantly associated with an increased amount of intra-operative blood loss and a prolonged

stay after surgery. These findings suggest that a prolonged operative time is associated with adverse clinical outcomes after SILC and can be predicted by several preoperative and operative factors, including BMI, acute cholecystitis and operator.

According to a recent meta-analysis of randomized controlled trials,<sup>7</sup> SILC had a significantly favourable cosmetic scoring compared with conventional LC, whereas the operating time was significantly longer in SILC. The mean operative time in the present series (155 min) was longer than the mean operative time of SILC (80 min; range, 40–186 min) reported in other papers.<sup>21</sup> This may be attributed to different gallbladder pathology (i.e. a relatively higher proportion of patients with acute cholecystitis), operator (almost one-fourth of SILC procedures were done by surgical residents) and a routine intra-operative cholangiography. In addition, the effect of a learning curve on the operative time was examined in the present study, because previous studies have suggested a correlation between learning curve and operative time in SILC.<sup>20,22</sup> However, there were no significant effects of learning curves, as assessed by the institution's first 100 patients and first 10 patients for each operator, on the operative time.

It has been shown that a prolonged operative time is associated with an adverse clinical course, i.e. increased complication rates in various laparoscopic surgery.<sup>13</sup> In conventional LC, a prolonged operative time has been reported to result in increased rates of post-operative complications (such as bile duct injury and bleeding) and a prolonged hospital stay.<sup>14</sup> In a retrospective analysis including a total of 601 patients undergoing a conventional LC, a significantly higher post-operative morbidity rate was noted in patients who had a procedure longer than 2 h than in patients whose surgery required less than 2 h (13.6% versus 3.6%,  $P < 0.001$ ).<sup>15</sup> In contrast, a study comparing patients whose conventional LC took 3 h or more and those whose operation took less than 3 h revealed no significant difference in the rate of post-operative complications.<sup>23</sup> In the present study, no significant difference was observed in the rate of post-operative complications between the prolonged operative time group (5%) and no prolonged operative time group (4%). However, this study has demonstrated that a prolonged operative time was significantly associated with a longer post-operative stay. One major concern raised against the present results is a relatively longer overall stay in patients undergoing SILC. In fact, the mean length of stay in patients undergoing SILC of less than 3 h was still long ( $5.4 \pm 3.3$  days). In general, the length of stay is longer in Japan as compared with other Western countries, primarily owing to the differences in the health insurance systems. Because the medical insurance in Japan covers the complete cost of hospitalization, most patients tend to stay longer in hospital until they recover completely from surgery. Various efforts are currently being made to shorten the length of stay and reduce the cost of medical care, for example, by introducing clinical pathways.

Previous studies have identified male gender, obesity, previous upper abdominal surgery, acute cholecystitis, intra-abdominal adhesions and low degree of surgical expertise as risk factors for

**Table 2** Univariate analysis for factors predicting a prolonged operative time in a single-incision laparoscopic cholecystectomy (SILC) between the no prolonged operative time group and the prolonged operative time group

Factor	No prolonged operative time group (n = 158)	Prolonged operative time group (n = 62)	P-value
Age (years)	62 (16–87)	63 (16–91)	0.5987
Gender (M/F)	91/67	31/31	0.3660
BMI (kg/m <sup>2</sup> )	22.1 (13.8–38.5)	24.3 (18.9–46.6)	0.0004 <sup>a</sup>
ASA score ( $\geq 3$ )	5 (3%)	2 (3%)	1.0000
Comorbid diseases (yes)	90 (57%)	35 (56%)	1.0000
Diabetes mellitus (yes)	18 (11%)	16 (26%)	0.0121 <sup>a</sup>
Prior abdominal surgery (yes)	62 (39%)	18 (29%)	0.1652
Prior upper abdominal surgery (yes)	7 (4%)	3 (5%)	1.0000
Acute cholecystitis (yes)	12 (8%)	18 (29%)	0.0001 <sup>a</sup>
Operator (residents/senior staff)	31/127	22/40	0.0219 <sup>a</sup>
Institution's first 100 cases	72 (46%)	28 (45%)	1.0000
First 10 cases for each operator	92 (58%)	41 (66%)	0.3579
WBC (/mm <sup>3</sup> )	5300 (2100–16900)	5600 (3500–11800)	0.0248 <sup>a</sup>
T. Bil. (g/dl)	0.6 (0.2–2.5)	0.6 (0.3–1.5)	0.5344
D. Bil. (g/dl)	0.2 (0.1–1.6)	0.2 (0.1–1.1)	0.3331
AST (IU/l)	23 (12–223)	22 (11–185)	0.2505
ALT (IU/l)	20 (7–362)	20 (6–350)	0.9540
ALP (IU/l)	244 (128–1973)	236 (144–1150)	0.9291
$\gamma$ -GTP (IU/l)	37 (7–536)	36 (13–1078)	0.4054
Creatinine (mg/dl)	0.7 (0.4–7.1)	0.7 (0.2–7.0)	0.5165

Values shown are median (range).

<sup>a</sup>Statistically significant.

BMI, body mass index; ASA, American Society of Anesthesiologists; WBC, white blood counts; T. Bil., total bilirubin; D. Bil., direct bilirubin; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase;  $\gamma$ -GTP, gamma-glutamyl transpeptidase.

**Table 3** Multivariate analysis for factors predicting a prolonged operative time in a single-incision laparoscopic cholecystectomy (SILC)

Factor	Category	Odds ratio	95% CI	P-value
BMI (kg/m <sup>2</sup> )	per 1 Kg/m <sup>2</sup>	1.1	1.0–1.2	0.0100 <sup>a</sup>
Diabetes mellitus	Yes/No	2.4	1.0–5.6	0.0507
Prior abdominal surgery	Yes/No	1.9	0.9–4.0	0.0819
Acute cholecystitis	Yes/No	6.2	2.5–16.2	<0.0001 <sup>a</sup>
Operator (residents)	Yes/No	4.0	1.9–8.6	0.0003 <sup>a</sup>
WBC (/mm <sup>3</sup> )	per 1 /mm <sup>3</sup>	1.0	1.0–1.0	0.6061

CI, confidential interval.

<sup>a</sup>Statistically significant.

BMI, body mass index; WBC, white blood counts.

predicting a prolonged operative time in conventional LC.<sup>14,16</sup> In the present study, the most significant risk factor for a prolonged operative time in SILC was acute cholecystitis. In current surgical practice, the indication of SILC may be limited to optimal cases without acute inflammation. However, a few previous studies have described the feasibility of SILC for the treatment of acute cholecystitis.<sup>24,25</sup> As a teaching hospital, SILC is attempted even in challenging patients, including those with severe acute cholecystitis. It is notable, however, that the mean operative time in patients with

acute cholecystitis was 220 min, which was significantly longer than in those without acute inflammation (145 min,  $P < 0.001$ ). These results may reflect, at least in part, greater technical difficulties of SILC for acute cholecystitis. Although the safety and benefits of SILC for acute cholecystitis should be evaluated in future studies, SILC for acute cholecystitis especially for obese patients may not be acceptable in the current surgical practice.

The present study has several limitations. First, this study is a retrospective analysis; therefore, the possibility of bias cannot be

**Table 4** Operative and post-operative outcomes of a single-incision laparoscopic cholecystectomy (SILC) in the no prolonged operative time group and prolonged operative time group

Factor	No prolonged operative time group (n = 158)	Prolonged operative time group (n = 62)	P-value
Intraoperative blood loss (ml)	5 (0–350)	5 (5–425)	0.0002 <sup>a</sup>
Post-operative complications	6 (3.8%)	3 (4.8%)	0.7141
Post-operative hospital stay (day)	5 (2–36)	6 (3–16)	0.0001 <sup>a</sup>

Values shown are median (range).

<sup>a</sup>Statistically significant.

eliminated. Second, SILC was performed by many surgeons with different experiences with this procedure in the present analysis. Although staff surgeons and residents were compared as a factor for a prolonged operative time, there may be differences in surgical skills even among staff surgeons. Furthermore, identification of a resident as a risk factor for a prolonged operative time may be because of limited experience as the mean patients per resident were only 5 as compared with 15 for a staff surgeon.

In summary, the results suggest that a higher BMI, acute cholecystitis and resident as an operator significantly increase the duration of the SILC procedure. Assessment of these factors may help to establish selection criteria for this procedure and facilitate the decision on the operating schedule as well as appropriate assignment of operator and assistant residents.

#### Conflicts of interest

None declared.

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